510(k) SUMMARY

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Summit Harmar, LLC
2075 47th Street
Sarasota, Florida 34234
Phone: (941) 351-2776
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JUL - 1 2009

Contact Person: Kevin Kaminski
Director, Global Sourcing and Logistics

Date Prepared: June 19, 2009

Name of Device

Pinnacle Stair Way Lift

Common or Usual Name

Stair Way Lift

Classification Name

Transport, Patient, Powered

Predicate Device

Bruno Electra-Ride Stair Way Elevator **(K033752)**

Intended Use

The Pinnacle Stair Way Lift is intended to assist transfers of patients or mobility impaired persons up and down flights of stairs.

Device Description

The Harmar Summit, LLC Pinnacle Stair Way Lift is a battery powered patient transport device designed for use in the home. It's intended function and use is to assist transfers of patients or mobility impaired persons up and down flights of stairs. It is intended for indoor use only.

The system is designed to carry a single patient, up a single flight of stairs while seated, at angle of between 27-45 degrees. Maximum travel distance is 75' at the maximum patient weight is 350 lbs. Maximum travel speed at full rated load is 20' per minute.

Substantial Equivalence

The Summit Harmar Pinnacle Stair Way Lift is substantially equivalent to the Bruno Electra-Ride Stair Way Elevator **(K033752).**

Performance Data

The Pinnacle Stairway lift is CSA and CUS listed under file number 226703. It has been certified by CSA to the following standards;

ASME A18.1	Safety Standards for Platform Lifts and Stairway Lifts
ASME A17.1	Safety Code for Elevators and Escalators

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 1 2009

Harmar Summit, LLC
% Spectre Solutions, Inc.
Mr. Edward Kroll
5905 Fawn Lane
Cleveland, Ohio 44144

Re: K091858
Trade/Device Name: Harmar Summit Pinnacle Stair Way Lift
Regulation Number: 21 CFR 890.5150
Regulation Name: Powered patient transport
Regulatory Class: II
Product Code: ILK
Dated: June 22, 2009
Received: June 23, 2009

Dear Mr. Kroll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): TBD

Device Name: Harmar Summit Pinnacle Stair Way Lift

Indications for Use:

The intended use of the Pinnacle Stair Way Lift is to assist transfers of patients or mobility impaired persons up and down flights of stairs.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K091858